Non-Final Rejection

Claims 1 and 3 are pending. No claim is allowed at this time. Amendments are entered.

Summary of this Office Action dated June 22, 2009

1. Continued Examination under 37 CFR 1.114
2. Information Disclosure Statement
3. Copending Applications
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5. 35 USC § 112 (2) Rejection
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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/09 has been entered.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information

within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim1 and 3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply:

3. Claim 1 is drawn to “a method of vitamin D derivative” and in third line “and the vitamin D derivative” is unclear. It is unclear what has been claimed.

Applicant is requested to redraft the claim to clearly point out the claimed invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the

subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3 rejected under 35 U.S.C. 103(a) as being unpatentable over **GAST et al. (J. Dairy Sci., 1979, 62:1009-1013, IDS reference),** WONG (US Patent 4,961,931), DUNCAN et al. (US Patent 3,545,439) , HARRISON et al (US Patent 6,572,874), WO 99/266556 (abstract, IDS reference), HESSE et al. (US 5,472,957).

GAST teaches the treatment of Parturient Paresis in cows which is characterized by hypocalcaemia by treating with 1, 25-dihydroxychleclaciferol intramuscularly. See the entire document especially abstract, results and discussion. The reference does not teach transvaginal administration.

WONG teaches a dispenser for vaginal administration and teaches the method for treating hyperplasia. See the entire document especially abstract, lines 16-24lines 1-21 in column 2lines 7-37 in column 9.

HARRISON teaches intravaginal administration of bisphosphonates into the blood circulation which improves systemic bioavailability of bisphosphonates by delivering **these compounds to the circulation transvaginally ten to thirty times higher than those delivered orally.** See the entire document especially lines 59-67 in column 5, lines 38-67 in column 6 and lines 1-14 in column 7.

DUNCAN teaches a device for transvaginal placement and retention useful for continued source of medication for sustained beneficial effects in female mammals, humans and animals. See the entire document especially abstractlines, 1-10 in column 1, lines 20-33 in column 2, and example 5.

WO 9926556 teaches an intra veginal device for delivering a pharmaceutical agent (e.g. progesterone) into a recipient mammal. The active agent is carried in matrix of a biodegradable polymer having an ability to provide desired retention characteristics of a variable geometry retention device, an appropriate release profile during a finite insertion period and biodegradability upon removal from the mammal. See the abstract.

HESSE et al teaches a method of treating osteoporosis, hypocalcaemia or bone disease by vitamin D. The reference also teaches veterinary applications of the vitamin D compounds, which includes the prevention of hypercalcemia in domestic animals, for example farm yard animals such as cattle and sheep

especially **cows** and ewes. See the entire document especially claim 7 and 11, abstract, lines 46-67 in column 6.

It would have been obvious to one skilled in the art to prepare additional beneficial compositions and for the treatment of hypercalcaemia/hypocalcemia by intra vaginal administration because the HARRISON reference teaches that systemic bioavailability of bisphosphonates **improves by delivering these compounds to the circulation transvaginally ten to thirty times higher than those delivered orally.** Since prior art teaches the uses of 1,25-dihydroxyvitamin D and it metabolic activity and the reference also teaches that improvement by transvaginal administration of drug and devices can be used to administer the drug therefore, having this knowledge at the time of invention one skilled in the art would have been motivated to use vitamin D for vaginal use. Present claims are obvious because vitamin D is known to treat hypercalcemia and transvaginal delivery of drugs have been known and taught by the prior art especially HARRISON teaches the advantages of transvaginal delivery.

It has been decided by the courts that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the

combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks

Applicant's arguments were fully considered but are not found persuasive for the same reasons as set forth in the previous office action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612